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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,000	11/28/2000	Anthony J. Polverino	MBHB00-450-A	6633

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/20/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,000

Applicant(s)

POLVERINO ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003 and 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 13-16, 46, 47 and 57-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 13, 14, 16, 46, 47, 57 and 59-61 is/are rejected.
- 7) ☒ Claim(s) 15, 58, and 62 is/are objected to.
- 8) ☒ Claim(s) 15, 46, 47, 58-60, and 62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on October 23, 2002 (Paper No. 20) has been entered.
2. The amendment filed October 23, 2002 in Paper No. 21 is acknowledged and has been entered. Claims 40-42 have been canceled. Claims 9, 13, 14, 16, 57, 58, 61, and 62 have been amended.
3. The declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed October 23, 2002 as part of Paper No. 21 is acknowledged and has been entered.
4. The amendment filed February 28, 2003 in Paper No. 20 is acknowledged and has been entered. Claims 9, 12-45, and 49-59 have been canceled. Claims 15, 58, and 62 have been amended.
5. Claims 9, 13-16, 46, 47, and 57-62 are pending in the application. Claims 9, 13, 14, 16, 57, and 61 and, in part, claims 15, 46, 47, 58-60, and 62 are currently under continued prosecution.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The declaration is defective because the declaration improperly lists US Application No. 09/599,087 as a "Prior Foreign Application", and therefore improperly claims benefit of the earlier filing date of US Application No. 09/599,087 under 35 USC §§ 120 and/or 121. Furthermore, as this application is a continuation-in-part of US Application No. 09/599,087, because of the impropriety of the declaration, Applicants' acknowledgment of the duty to disclose to the Office all the information that is material to the patentability as defined in 35 USC § 1.56, which became available between the filing date of the prior application and the filing date of this application, is questionable.

Election/Restrictions

7. Newly amended claims 15, 46, 47, 58-60, and 62 are directed, in part, to inventions that are independent or distinct from the invention originally claimed for the following reasons:

Claims 15, 58, and 62 are drawn to a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 22. Therefore, claims 15, 58, and 62 encompass the elected invention, i.e., a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5. However, claims 15, 58, and 62 also encompass the non-elected invention of group 3, as identified in the Office action mailed April 27, 2001 (Paper No. 7). Additionally, claims 15, 58, and 62 encompass a multitude of other distinct inventions, or distinct polypeptides comprising amino acid sequences that differ from the amino acid sequence of the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15, 46, 47, 58-60, and 62, to the extent that the claims are drawn to non-elected inventions, are withdrawn from consideration as being directed to a non-elected invention. In other words, claims 15, 58, and 62 are only considered herein to the extent that the claims are drawn to a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to the Declaration under 37 CFR § 1.131

8. The declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed October 23, 2002 as part of Paper No. 21 is sufficient to overcome the FAPESP/LICR Human Cancer Genome Project (GENBANK Accession No. AW351839) reference.

Although the declaration does not provide an explicit showing that establishes the conception, or a reduction to practice of a polypeptide produced by a process comprising culturing a host cell containing a nucleic acid molecule comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1449, according to claim 9, the DNA insert to which the claims refer is the same as a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide as set forth in SEQ ID NO: 5. Because the declaration provides a showing sufficient to antedate the FAPESP/LICR Human Cancer Genome Project (GENBANK Accession No. AW351839, 01 February 2000) reference, which includes evidence of conception, and reduction to practice of a nucleic acid molecule having the polynucleotide sequence set forth in SEQ ID NO: 4 encoding the amino acid sequence of SEQ ID NO: 5, the declaration is also deemed to provide a suggestion of the conception, if not a reduction to practice of a polypeptide produced by a process comprising culturing a host cell containing a nucleic acid molecule comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1449.

Grounds of Objection and Rejection Withdrawn

9. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed April 23, 2002 (Paper No. 14) have been withdrawn.

For clarity of record, the grounds of rejection of claims 9, 13, 16, 46, 47, 57, and 59-61 under 35 USC § 112, second paragraph set forth in section 16(b) of the previous Office action mailed April 23, 2002 (Paper No. 14) have been withdrawn for the following reason:

Even though the polynucleotide sequence of the DNA insert of ATCC Deposit No. PTA-1755 is not actually described in the specification, the DNA insert is defined at page 2, lines 27-30, to be a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. Therefore, it is clear that the polynucleotide sequence of the claimed DNA insert differs from SEQ ID NO: 4, but nevertheless the claimed DNA insert must necessarily encode the human SECS-1 polypeptide, i.e., SEQ ID NO: 5, in accordance with claim 9. Moreover, the specification discloses that the DNA insert of ATCC Deposit No. PTA-1755 is a nucleic acid molecule encoding the human SECS-1 polypeptide, which was subcloned into a vector designated p7T73D (page 85, lines 11-15). The resultant clone was deposited on April 25, 2000 and, therefore, the deposit, once perfected according to the requirements set forth by the Budapest Treaty, will be deemed to suffice to describe the DNA insert to which the claims are drawn. The DNA insert of the claims is thus regarded as the portion of the cloned nucleic acid molecule in the deposit having ATCC Deposit No. PTA-1755, which encodes the human SECS-1 polypeptide, and which does not comprise a portion of the parental cloning vector, p7T73D.

The grounds of rejection of claims 57 and 59-61 under 35 USC § 112, first paragraph set forth in section 23 of the previous Office action mailed April 23, 2002 (Paper No. 14) have been withdrawn for the following reason: Support for the recitation of "a region of" the sequences is found in the disclosure in the paragraph bridging pages 2 and 3.

Specification

10. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of improperly demarcated trademarks include GENBANK (page 85), L and DYNABEADS (page 86), Clontech™ (page 87), BIOSOURCE (page 87),

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AMBION (page 88), KODAK (page 89), QIAQUICK (page 89), Qiagen™ (pages 89), READY TO GO (page 89), Invitrogen™ (page 93), BIOGENEX (page 97), BIOTEK (page 97), and PHARMINGEN (page 98).

Appropriate corrections are required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

Claim Objections

11. Claims 15, 46, 47, 58-60, and 62 are objected to because of the following informalities:

Claims 15, 46, 47, 58-60, and 62 are objectionable because the claims are drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 14, 46, 47, 57, and 59-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14, 57, and 61 recite, "but not more than 80 amino acid residues". In Paper No. 21, Applicants have remarked that support for the amendments can be found

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in the specification at, for example, page 2, page 3, page 23, and in Figures 2 and 3. However, the disclosures and the figures to which Applicants have referred do not appear to be proper and sufficient antecedent basis for recitation of this limitation in the claims. Accordingly, the recitation of the limitation in the claim appears to introduce new matter and thereby violates the written description requirement of 35 USC § 112, first paragraph.

This issue might be resolved if Applicants were to point to specific disclosures in the specification that are believed to provide the necessary support.

14. The specification is objected to and claims 9, 13, 16, 46, 47, 57, and 59-61 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g., the disclosure of the claimed nucleic acid molecule's polynucleotide sequence); or (3) deposited.

Claims 9, 13, 16, 57, and 61 are drawn to polypeptide produced by a process comprising culturing a host cell containing a nucleic acid comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755. However, because the polynucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755 is not set forth in the specification, it is apparent that the DNA insert in ATCC Deposit No. PTA-1755 would be required to make and use the claimed invention. As a required element, the DNA insert in ATCC Deposit No. PTA-1755 must be known and readily available to the public, or otherwise obtainable by a repeatable method set forth in the specification. If it is not so available or obtainable, a deposit containing the claimed nucleic acid molecule may satisfy the enablement requirements of 35 USC 112, first paragraph. See 37 CFR §§ 1.801-1.809.

The referral to the deposit at page 85 of the specification is insufficient assurance that all required deposits have been made and all the conditions of MPEP 608.01 (p)(c) are met.

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If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Stephen L. Rawlings, Ph.D.

Examiner

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slr

May 16, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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